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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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23552	7590	01/16/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 01/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/957,434

Applicant(s)

YIV ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

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DETAILED ACTION

The following office action is a responsive to the amendments filed on 10/22/03 in which a provisional election was made with traverse to prosecute the invention of Group I, claims 1-58.

The response has the following effect:

1. Claims 1-52, the invention of Group I are prosecuted by the examiner.

Claims 59-61 are amended. New claim 74 has been added. Claims 53-74 are withdrawn.

2. The responsive is contained herein below.

Upon further review of the Election restriction requirement the examiner has found that claims 53-58 which are process claims, unlike the claims 1-52 which are composition claims, are withdrawn from consideration from consideration and from Group I. Thus, the following amended Election restriction requirement is included below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-52, drawn to a spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, classified in class 514, subclasses 50, 78, 49, class 536, subclasses, 123.1, 114, class 554, subclass 1+, class 556, subclass 42, class, 564, subclass 17.
- II. Claims 59-61, drawn to a method for inhibiting the motility of sperm, classified in class 514, subclasses 50, 78, class 536, subclasses 114, 123.1, class 554, subclass 1+

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- III. Claims 62-73, drawn to a pharmaceutical composition adapted for the topical delivery of a therapeutic agent, classified in class 514, subclasses 50, 78, class 536, subclasses 114, 123.1, class 554, subclass 1+, class 530, subclass 852.
- IV. Claims 53-58, drawn to a process for preparing a pharmaceutical composition of claim 1, classified in class 514, subclasses 50, 78, 49, class 536, subclasses, 123.1, 114, class 554, subclass 1+, class 556, subclass 42, class, 564, subclass 17.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product. For example, other spermicidal composition like Nonoxynol-9 (or N-9) and menfegol can be used to practice the said process.
2. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

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3. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

4. Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product like compositions that are non-spermicidal.

5. Inventions II and IV and III and IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claims 1-52 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5,11-13,16,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nath (IN 93772) in view of Fost et al. (US 5,215,976).

In claim 1, applicants claim, "A spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein the oil-in-water microemulsion comprises a lipid, one or more pharmaceutically acceptable surfactants, one or more pharmaceutically acceptable humectants and water."

Nath discloses a spermicidal composition of an oil-in-water emulsion, wherein the oil-in-water emulsion comprises a surfactant (a glycol ester of stearic acid), alkylphenoxy poly

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(ethylenoxy) ethanol, stearic acid, glycerol and water. (see abstract). In addition, Nath discloses a spermicidal composition which is in a gel form, and which comprises a humectant (polyethylene glycol), a hydrogel (sodium carboxymethylated cellulose or Na CM-cellulose), alkylphenoxypoly (ethylenoxy) ethanol, and water (see abstract).

Fost et al. disclose that phospholipids can be used in spermicidal compositions (see abstract and col. 1, lines 23-53).

The difference between applicants' claimed composition and the composition of Nath is that applicant's composition contains a combination of the ingredients found in Nath's two compositions (surfactant, humectant, water and polymeric hydrogel) in addition to a lipid. However, Fost et al. disclose that phospholipids can be used in spermicidal compositions and has spermicidal activity.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Nath and Fost et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and to include any phospholipid like the phospholipid disclosed Fost et al., since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Nath and Fost et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and to include any phospholipid like the phospholipid disclosed Fost et al., since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art.

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More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that dependent claims 2-5,11-13,16,19 are also encompassed by the aforementioned rejection. Also, the use of preservatives in spermicidal compositions (as recited in claim 16) and, the use of cream forms (as recited in claim 19) of spermicidal compositions are obvious and well known in the art.

Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nath and Fost et al. as applied to claim 1 above, and further in view of Uckun et al. (Book of Abstracts, 216th ACS National Meeting, Boston, August 23-27 (1998), MEDI-211. American chemical Society: Washington D. C.).

In claim 20, applicant claims "The composition of claim 1 further comprising one or more therapeutic agents"

Uckun et al. disclose that the AZT derivative, 5-bromo-6-methoxy-5,6-dihydro-3'-azidothymidine-5-(p-bromophenyl)-methoxyalaninyl phosphate is a spermicidal agent (see abstract).

The difference between applicants' claimed composition and the composition of Nath in view of Fost et al. is that applicant's composition also contains a therapeutic agent. However, Uckun et al. disclose that the AZT derivative, 5-bromo-6-methoxy-5,6-dihydro-3'-azidothymidine-5-(p-bromophenyl)-methoxyalaninyl phosphate is a spermicidal agent.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Nath, Fost et al. and Uckun et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and Fost et al. to

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include a therapeutic agent like an AZT derivative 5-bromo-6-methoxy-5,6-dihydro-3'-azidothymidine-5-(p-bromophenyl)-methoxyalaninyl phosphate of Uckunet al., since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Nath, Fost et al. and Uckun et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and Fost et al. to include a therapeutic agent like an AZT derivative 5-bromo-6-methoxy-5,6-dihydro-3'-azidothymidine-5-(p-bromophenyl)-methoxyalaninyl phosphate of Uckunet al., since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that claims 21-24 are also encompassed by this rejection..

Claims 20,28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nath and Fost et al. as applied to claim 1 above, and further in view of D'Cruz et al. (US 6,051,603).

In claim 28, applicant claims "The composition of claim 20, wherein the therapeutic agent comprises a vanadium (IV) complex, or a pharmaceuucally acceptable salt thereof."

D'Cruz et al. disclose that vanadium complexes exhibits spermicidal activity (see abstract).

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The difference between applicants' claimed composition and the composition of Nath in view of Fost et al. is that applicant's composition also contains a therapeutic agent. However, D'Cruz et al. disclose that vanadium complexes exhibits spermicidal activity.

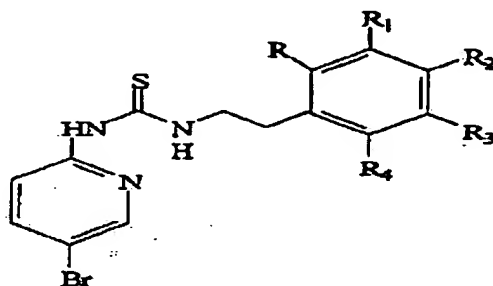
It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Nath, Fost et al. and D'Cruz et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and Fost et al. to include a therapeutic agent like any vanadium complex, since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Nath, Fost et al. and D'Cruz et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and Fost et al. to include a therapeutic agent like any vanadium complex, since the combination of compounds that are used for the same purpose (e.g. as spermicidals) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that claims 29-35 are also encompassed by this rejection

Claims 20,36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nath and Fost et al. as applied to claim 1 above, and further in view of Uckun et al. (US 6,136,335).

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In claim 36, applicant claims "A composition according to claim 20, wherein the therapeutic agent is a phenethyl-5-bromopyridylthiourea derivative of the following chemical formula, or pharmaceutically acceptable salt thereof:



wherein

Uckun et al. disclose that the phenethyl-5-bromopyridylthiourea derivative, F-PBT exhibits spermicidal activity (see abstract and structures on page 1).

The difference between applicants' claimed composition and the composition of Nath in view of Fost et al. is that applicant's composition also contains a therapeutic agent. However, Uckun et al. disclose that phenethyl-5-bromopyridylthiourea derivative including N-[2-(2-fluorophenethyl)]-N'-[2-(5-bromopyridyl)]-thiourea (F-PBT) is a spermicidal agent.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Nath, Fost et al. and Uckun et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and Fost et al. to include a therapeutic agent like the phenethyl-5-bromopyridylthiourea derivative of Uckun et al., since the combination of compounds that are used for the same purpose (e.g. as spermicidal) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

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One having ordinary skill in the art would have been motivated, in view of Nath, Fost et al. and Uckun et al., to prepare a composition comprising a combination of all the ingredient taught by Nath and Fost et al. to include a therapeutic agent like the phenethyl-5-bromopyridylthiourea derivative of Uckun et al., since the combination of compounds that are used for the same purpose (e.g. as spermicidal) are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that claims 37 is also encompassed by this rejection. Also, claim 38 which is dependent on claim 20 and is drawn to dihydroxalkoxybenzylpyrimidine derivatives, is also encompassed by this rejection since Uckun et al. also disclose that dihydroxalkoxybenzylpyrimidine derivatives including applicant's derivative, 5-isopropyl-2-[(methylthiomethyl)thio]-6-benzyl-pyrimidin-4-1H-one (S-DABO) have spermicidal activity (see abstract and structures on page 1).

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 6-10,14,5,17,18,40-52 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record provided that they are rewritten an acceptable independent form or they are not dependent on a rejected claim and that no new subject matter are added to these claims. The present invention relates a spermicidal composition comprising a gel-microemulsion comprising an oil-in-water microemulsion and a polymeric hydrogel, wherein

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the oil-in-water microemulsion comprises a lipid, one or more pharmaceutically acceptable surfactants, one or more pharmaceutically acceptable humectants and water. The very relevant prior art documents (Nath, (IN 93772)) to this invention discloses a spermicidal compositions including an oil-in-water emulsion.

However, though compositions of prior art document are similar those of the instant invention, the compositions of claims 6-10,14,5,17,18,40-52 of the instant invention, which are characterized by further limitations, are different and unobvious to those of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

January 9,2004.

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PRIMARY EXAMINER
GROUP 1200